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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,592	03/19/2004	William Galbraith	80154	9558
26253 7590 09/10/2009 David W. Highet, VP & Chief IP Counsel Becton, Dickinson and Company 1 Becton Drive MC 110 Franklin Lakes, NJ 07417-1880				
EXAMINER YU, MELANIE J				
ART UNIT		PAPER NUMBER		
1641				
MAIL DATE		DELIVERY MODE		
09/10/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/804,592

**Applicant(s)**

GALBRAITH, WILLIAM

**Examiner**

MELANIE YU

**Art Unit**

1641

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 5, 6 and 55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 6 and 55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date 5/29.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application.
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

1. Applicant's amendment filed 12 June 2009 has been entered.

***Status of the Claims***

2. Claims 1, 5, 6 and 55 are currently pending and are examined on the merits.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
1. Claims 1, 5, 6 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grahnén et al. (The preparation of Ligandin with Glutathione-S-Transferase Activity from Porcine Liver Cytosol by Affinity Chromatography on Bromosulphophthalein-Sepharose, 1977, Eur. J. Biochem., Issue 80, pages 573-580) in view of Spring et al. (US 5,643,721) further in view of Degen et al. (US 5,567,615).

Grahnén et al. teach an apparatus comprising an insoluble support (sepharose column) having a ligand consisting of bromosulphophthalein attached thereto, which is capable of being bindable to albumin, without being exposed to albumin (pg. 574, section: *Preparation of Bromosulphophthalein Affinity Column*). Grahnén et al. fail to teach the ligand attached to the support via an epoxy linkage.

Spring et al. teach ligands attached to an agarose substrate by an epoxy linker may be an agarose substrate (col. 5, lines 50-55), in order to provide a mixture that dries in a film form on the surface to which it is applied.

Degen et al. teach a ligand having a hydroxyl group (col. 12, line 46) attached to a polymer support via an epoxy linker (col. 12, lines 41-47) and therefore teach attachment of a ligand that is epoxy-activated (epoxy linker activates the support, col. 13, lines 44-46), in order to provide attachment of ligands to a polymer substrate.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the apparatus of Grahnén et al., an epoxy linkage between the ligand and the agarose support as taught by Spring et al., in order to provide a simple method of attaching ligands having a hydroxyl group to a substrate by way of a spontaneous covalent attachment as taught by Degen et al. Degen et al. do not specifically teach a bromosulphophthalein ligand being attached to an agarose support. However, Degen et al. teach that epoxy linker attachment is advantageous for ligands having a hydroxyl group and Spring et al. teach that an epoxy linker is advantageous to link ligands to an agarose support. Since bromosulphophthalein comprises a hydroxyl group, Degen et al. teach the epoxy linkage would be a simpler

and advantageous method of attachment of bromosulphophthalein to a substrate, and Spring et al. teach that it would have been obvious for the substrate that the epoxy linker attaches to, to be an agarose support. Therefore an epoxy linker is advantageously used to attach the ligand to the agarose substrate of Grahnen et al.

With respect to claims 5, 6 and 55, Grahnen et al. teach that the insoluble support is contained in and supported in a column (affinity column with bromosulphophthalein as a ligand, pg. 574, section: *Preparation of Bromosulphophthalein Affinity Column*; and pg. 575, right column, last 2 paragraphs) wherein the support is cross-linked sepharose, which is a type of agarose (pg. 574).

### ***Response to Arguments***

3. Applicant's arguments regarding the previous rejections under 35 USC 112, first paragraph have been considered and are withdrawn in light of the cancellation of claim 54.
2. Applicant's arguments filed 12 June 2009 with respect to the rejections under 35 USC 103(a) have been fully considered but they are not persuasive.

At pages 3-5 applicant argues that at pages 579-580 Grahnen et al. teach that the binding characteristics of BSP are alterable and therefore one skilled in the art would not look to alter the Grahnen et al. procedure and utilize epoxy linkers. Applicant further argues that there is no predictability in the characteristics of the resulting BSP in changing the linking methodology, specifically by using an epoxy linker.

Applicant's argument is not persuasive because at pages 579-580 Grahnen et al. discuss that the increased specific activity may be due to differences in isolation

methods. Nowhere does Grahnen et al. describe that a linker between the BSP and the support affects the binding characteristics of BSP. The passage describing the alterable binding characteristics of BSP at pages 579-580 of Grahnen et al. is therefore not relevant to the affect of a linker on the binding characteristics of BSP. Furthermore, Grahnen et al. do not teach away from using a linker to attach BSP to the support. Therefore one having ordinary skill would expect BSP to retain its binding characteristics and would have been motivated to utilizing an epoxy linker between the BSP and the sepharose support as described above. One having ordinary skill would also have a reasonable expectation of success in using the epoxy linker with BSP since the prior art teaches an epoxy group linked to a hydroxyl group on a ligand and the BSP ligand contains a hydroxyl group.

### ***Conclusion***

3. No claims are allowed.
4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE YU whose telephone number is (571)272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Yu/  
Patent Examiner, Art Unit 1641